

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION) MDL 2804
THIS DOCUMENT RELATES TO:) Case No. 1:17-md-2804
Track Three Cases) Judge Dan Aaron Polster
) OPINION AND ORDER DENYING
) DEFENDANTS' MOTION TO
) EXCLUDE OPINIONS AND
) TESTIMONY OF CRAIG MCCANN

Before the Court is Defendants' Motion to Exclude the Opinions and Testimony of Craig McCann. Plaintiffs (Ohio's Lake and Trumbull Counties) filed a response, and Defendants filed a reply. For the reasons stated below, the Motion is **DENIED**.

Craig McCann, a data expert,¹ provides calculations applying certain criteria to: (1) Defendants' *distribution* data, to identify potentially suspicious opioid orders; and (2) Defendants' *dispensing* data, to identify potentially illegitimate opioid prescriptions. At the distribution level, McCann applies seven threshold formulae (devised by former DEA Investigator James Rafalski) to the DEA's Automation of Reports and Consolidation Orders System ("ARCOS") data and Defendants' transactional data; these formulae identify potentially suspicious opioid orders placed

¹ Defendants do not challenge McCann's qualification as an expert. For information on McCann's credentials and experience, see *T1 Daubert Order re Rafalski and McCann, In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 3934490, at *7 (N.D. Ohio Aug. 20, 2019) (Doc. #: 2494 at 15) and McCann T3 Report at 1-2, Appx. 1.

by Defendants' pharmacies in the *Track Three* Counties. The *Track Three* Defendants do not challenge McCann's application of Rafalski's methods to their distribution data.²

At the dispensing level, McCann applies 16 "red flag" criteria (devised by pharmacist Carmen Catizone) to Defendants' dispensing data to identify potentially illegitimate opioid prescriptions dispensed by these same pharmacies.³ Defendants do not challenge McCann's interpretation of Catizone's flagging methodology, nor McCann's calculations of the underlying dispensing data.⁴ But Defendants do object that, because the Court's discovery orders limited the evidence Plaintiffs are allowed to present at trial regarding "red-flagged prescriptions," McCann's calculations now yield an arbitrary "compilation" or "manipulation of data" that renders his opinions unreliable or unhelpful. For the reasons discussed below, the Court disagrees.

I. Legal Standard.

The Court incorporates by reference the applicable legal standards set forth in its *Track One Order Denying Motion to Exclude Rosenthal* (Doc. #: 2495 at 1-10).⁵

² In both *Track One* and *Track Three*, the Court found McCann's application of threshold formulae to flag potentially suspicious orders at the distribution level would be relevant and helpful to the fact finder's determination of material issues in the case. *See T1 Daubert Order re Rafalski and McCann, In re Opiate*, 2019 WL 3934490, at *8-9 (Doc. #: 2494 at 18-19); *T3 Daubert Order re Rafalski, In re Opiate*, No. 1:17-MD-2804, 2021 WL 40603599, *1, *5-6 (Sept. 7, 2021) (finding Rafalski, as a former DEA Investigator, has reliable expertise to identify methods available to flag potentially suspicious orders) (Doc. #: 3929 at 1, 8-11).

³ According to Catizone, "red-flag" prescriptions present certain warning signs and create a reasonable suspicion that triggers a pharmacy's and pharmacist's duty to determine if the prescription is valid and issued for a legitimate medical purpose. *See T3 Catizone Report* at 27-28.

⁴ By separate motion, Defendants challenged the reliability of Catizone's flagging methodology and Defendants do challenge McCann's opinions to the extent they depend on Catizone's opinions. As discussed *infra*, this argument is moot in light of the Court's order denying this aspect of Defendant's motion to exclude Catizone's opinions. *See T3 Daubert Order re Catizone* (Doc. #: 3947).

⁵ *In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804, 2019 WL 3934597, at *1-5 (N.D. Ohio Aug. 20, 2019).

II. Background: Plaintiffs' Disclosures of "Red-Flag" Prescriptions

The essential basis for Defendants' present challenge is born from the Court's discovery rulings related to identification by Plaintiffs of which "red flag prescriptions" they would rely upon at trial. In its *Track Three* Case Management Order ("CMO"), the Court ordered Plaintiffs to identify for Defendants the following information by June 19, 2020:

- (i) the prescriptions they (and their experts) conclude caused them the harm for which they seek relief;
- (ii) the methodology or methodologies they (and their experts) used to reach such a conclusion; and
- (iii) the electronic scripts or analytical programs used by Plaintiffs and/or their experts to implement that methodology.

T3 Case Mgmt. Order at 3 (Doc. #: 3329). Notably, this June 19 deadline came well before the deadline for Plaintiffs to submit their expert reports. *Id* at 5.

Pursuant to this CMO, Plaintiffs disclosed approximately one million prescriptions they alleged caused the harm for which they intended to seek relief. Plaintiffs identified these prescriptions by applying 27 "red flag" algorithms to Defendants' dispensing data.⁶ The reason the CMO required Plaintiffs to disclose these prescriptions before the *Track Three* expert report deadline (even though the topic required at least some level of expert analysis) was that Defendants insisted (and the Court agreed) that they needed *some* idea of the scope and texture of Plaintiffs' dispensing claims during *fact* discovery, which closed before any expert reports were due.

⁶ Plaintiffs' designed their "red flag" algorithms to identify opioid prescriptions they allege were suspicious and possibly illegitimate, such that the Pharmacy Defendants should not have dispensed the prescriptions absent due diligence to clear the suspicion. Examples of these algorithms include: (i) questionable drug combinations (e.g. red flag no. 39, where "[a]n opioid, a benzodiazepine and a muscle relaxer were dispensed to a patient on the same day and all the prescriptions were written by the same prescriber"); (ii) indicia of doctor shopping (e.g. red flag no. 20, where a "patient was dispensed opioid prescriptions written by at least 3 different prescribers such that all the opioid prescriptions were written in a 45-day period"); and (iii) excessive dispensing (e.g. red flag no. 35, where a "patient received opioid prescriptions from the same prescriber on at least 4 dates within a 45-day period"). See docket no. 3719-1 (listing all red flag algorithms).

Ten months later, in April of 2021, Plaintiffs disclosed the expert reports of McCann and Catizone, which together identified approximately two million “red-flagged,” potentially illegitimate opioid prescriptions dispensed by Defendants’ pharmacies. *See* T3 McCann Rpt. at 150-180; *Amended Order re: Red Flagged Prescriptions* at 1 (Doc. #: 3726). More specifically, McCann identified these two million “red-flagged” prescriptions by applying a total of 43 “red flag” algorithms to Defendants’ dispensing data, including: (1) the 27 original “red flags” used by Plaintiffs to identify the prescriptions they had disclosed in June of 2020 (“red flag” numbers 17-43 in McCann’s Report); and (2) 16 new “red flags” devised by Catizone (“red flag” numbers 1-16 in McCann’s Report). Many of Catizone’s new “red flag” algorithms were similar to, or were simplifications or refinements of, Plaintiffs’ original “red flag” algorithms,⁷ but the addition of these 16 new algorithms worked to identify about one million additional “red flag” prescriptions.

Specifically, by combining both sets of criteria – that is, the 27 original “red flags” plus Catizone’s 16 new “red flags” – McCann’s Report identified roughly one million more “red flagged” prescriptions than Plaintiffs had disclosed in June of 2020. *See Amended Order re: Red Flagged Prescriptions* at 1 (Doc. #: 3726). At the time, it appeared that approximately 840,000 of these two million prescriptions “overlapped,” meaning they were identified as possibly suspicious by **both** Catizone’s 16 “red flags” and the 27 original “red flags.” *Id.*

⁷ For example, under the rubric of doctor-shopping, Plaintiffs’ original red flag no. 20 identifies prescriptions where the “[p]atient was dispensed opioid prescriptions with overlapping days of supply that were written by two or more prescribers,” while Catizone’s red flag no. 3 identifies circumstances where a “patient was dispensed opioid prescriptions written by at least 3 different prescribers such that all the opioid prescriptions were written in a 45-day period.”

As another example, with their original red flag no. 32, Plaintiffs identified as suspicious those circumstances where the “patient was [i] dispensed more than 90 dosage units of the same opioid base drug, strength and dosage form at least twice in a 20-day period and [ii] the patient paid cash for at least one of the prescriptions.” In contrast, Catizone separated these concerns into separate algorithms: his red flag no. 16 identified as suspicious all opioid prescriptions where the patient paid cash, while his red flag nos. 10, 11, 14, & 15 each identified as suspicious prescriptions where the patient received possibly excessive opioid doses. *See* docket no. 3719-1 (listing all red flag algorithms).

After McCann issued his expert report, Defendants moved to strike the additional one million red-flagged prescriptions identified by Catizone's new flagging criteria, arguing Plaintiffs did not timely disclose them. *See* Mtn. to Strike (Doc. #: 3716). Following briefing on the motion, the Court gave Plaintiffs three choices – they could: (1) rely upon only the original one million prescriptions disclosed in June of 2020 and keep the fall 2021 trial date; (2) rely upon the 840,000 “overlapping” prescriptions and keep the fall 2021 trial date; or (3) rely upon all of the two million prescriptions, but the trial would be continued to the spring of 2022 to allow Defendants additional time for discovery regarding the additional “red flag” prescriptions. *Amended Order re: Red Flagged Prescriptions* at 1-2 (Doc. #: 3726). Notably, the second option was originally Defendants’ own suggestion. *See* Defs. Reply ISO Mtn. to Strike at 2-3 (Doc. #: 3722) (“If the Court neither grants Defendants’ motion to strike Plaintiffs’ untimely red flags (and the million-plus new prescriptions they flag), nor gives Defendants additional time to conduct discovery on this new information, then the Court should at the very least preclude Plaintiffs from referencing at trial any flagged prescriptions other than the 840,000 overlapping prescriptions”).

Plaintiffs elected the second option and agreed to limit their “universe” of evidence regarding “red-flagged” prescriptions at trial to the overlapping prescriptions. Of course, these were actually a subset of the original one million prescriptions disclosed in June of 2020. McCann then prepared a Second Supplemental Report⁸ reflecting his calculations that yielded 884,166 “overlapping” prescriptions that were both: (1) flagged by Catizone; and (2) timely disclosed by Plaintiffs.

⁸ McCann’s Second Supplemental Report is dated May 19, 2021. McCann’s initial *Track Three* Report is dated April 16, 2021. McCann T3 Rpt. On May 4, 2021, McCann prepared a First Supplemental Report to account for the results of applying flagging algorithms to ARCOS data supplemented with missing transactions, and to correct a typographical error. *See* McCann T3 1st Supp. Rpt. at 6, ¶ 4.

II. Analysis.

Defendants urge the Court to exclude McCann's opinions and testimony on "red flag" dispensing data, arguing: (1) McCann's calculations depend on the opinions of Carmen Catizone, whom Defendants seek to exclude by separate motion; and (2) McCann's calculations compiling the "overlapping" subset of 884,166 "red flag" prescriptions is unreliable and does not "fit" the facts of this case.

1. Dependency on Catizone's Opinions.

Defendants argue that, if the Court excludes Catizone's opinions, it must also exclude McCann's "red flag" dispensing computations. Specifically, Defendants assert that, because McCann is purely a data expert with no independent knowledge of "red flag" dispensing criteria – and because Catizone is Plaintiffs' only expert who opines on the validity of the "red flags" – McCann's dispensing computations necessarily depend on the admissibility of Catizone's opinions.

Plaintiffs respond that many of the "red flag" criteria are independently supported by evidence other than Catizone's opinions, including Defendants' own documents.⁹ Response at 2-5. Indeed, McCann's Report states that, in addition to Catizone's opinions, McCann's criteria for flagging prescriptions are derived from a number of sources, including Defendant's own policies and procedures, DEA guidance, court decisions, pronouncements by State Boards of Pharmacy,

⁹ For instance, Plaintiffs point to Defendants' own documents recognizing as "red flags:" (1) a combination of an opioid, benzodiazepine, and a muscle relaxer; and (2) dispensing opioids to patients at multiple pharmacies. Response at 3-4 (citations omitted). These criteria are found in McCann's red flags numbered 5, 6, 22, 23, 24, 39, and 41. McCann T3 Rpt. at 150-156.

and literature produced by industry trade groups. McCann T3 Rpt. at 150-180. Based on these representations, it appears likely that – even without Catizone – Plaintiffs could establish an evidentiary foundation for at least some of McCann’s flagging criteria.

The Court need not decide this matter, however, because it has overruled this aspect of the motion to exclude Catizone. *See T3 Daubert Order re Catizone* (Doc. #: 3947). Accordingly, Defendants’ motion to exclude McCann on this ground is denied as moot.

2. Reliability of “Red Flag” Dispensing Analysis

Defendants assert McCann’s supplemental calculations identifying the 884,166 “overlapping” prescriptions are inherently arbitrary and unreliable because they do not reflect the actual number of prescriptions (about two million) Catizone actually identified using his 16 “red flag” criteria. Motion at 6. More specifically, Defendants argue McCann’s supplemental calculations identifying the subset of “overlapping” prescriptions constitute an arbitrary “compilation” or “manipulation of data” that does not accurately reflect the true number of prescriptions actually identified by Catizone’s own flagging methodology. Reply at 5-7.

Defendants’ argument overlooks the fact that Catizone’s same “red flag” methodology identifies as potentially suspicious both the “overlapping” subset of 884,166 prescriptions and Catizone’s original two million flagged prescriptions.¹¹ As noted, the Court has found Catizone’s methodology to be reliable. *T3 Catizone Daubert Order* (Doc. #: 3947). At bottom, Defendants’ objection essentially goes to the fact that the number of “overlapping” prescriptions is different than – and therefore does not “accurately” reflect – the total number of prescriptions actually flagged by Catizone. But it was Defendants who objected to introduction at trial of the “actual

¹¹ Indeed, Defendants do not dispute “the interpretation or quality of the underlying data.” Reply at 7.

universe” of prescriptions initially flagged by Catizone, and who suggested, as one possible solution, that “the Court should . . . preclude Plaintiffs from referencing at trial any flagged prescriptions” other than the “overlapping” prescriptions both identified by Catizone and disclosed in June of 2020. Reply ISO Mtn. to Strike at 3 (Doc. #: 3722). Moreover, the net effect is that Plaintiffs are now limited at trial to relying upon *fewer* “red flag” prescriptions than they originally identified in June of 2020, and *fewer* “red flag” prescriptions than Catizone identified in his expert report. The Court’s discovery and evidentiary rulings do not undermine Catizone’s or McCann’s methodology.

Under these circumstances, the Court finds McCann’s supplemental calculations are not unreliable nor manipulated such that they are disconnected from the facts of the case. That the Court’s prior rulings ultimately limited Plaintiffs’ ability to present evidence does not make McCann’s calculations arbitrary or unreliable. Nevertheless, if Defendants believe information regarding the total number of prescriptions identified by Catizone’s 16 “red flags” alone (about two million) are relevant to the jury’s determination of the weight it should give to McCann’s (or Catizone’s) opinions at trial, then Defendants are free to adduce evidence regarding Catizone’s full analysis and how it compares with the subset of 884,166 “red flag” prescriptions upon which Plaintiffs are allowed to rely.

Finally, the Court notes that, in their reply brief, Defendants ask the Court to bar McCann and Plaintiffs from referring to any “unvalidated” dispensing algorithms as “red flags.” Reply at 1, 3. Defendants assert no expert ever evaluated the validity or basis for any of the 27 original “red flag” algorithms used by Plaintiffs, so neither Plaintiffs nor their experts may rely upon them now. Plaintiffs point to an array of evidence, however – including Defendants’ own documents, court decisions, DEA guidance, and so on – that support (to varying extents) the design and

contours of *all* of the 43 “red flags” used by McCann. Whether a given “red flag” algorithm does, in fact, identify a prescription as suspicious goes to the weight of McCann’s and Catizone’s opinions. Defendants will have full latitude at trial to examine these experts and other witnesses regarding whether a “red flag” is “valid.”

III. Conclusion.

For the reasons stated above, Defendants’ Motion to Exclude the Opinions and Testimony of Craig McCann is **DENIED**.

IT IS SO ORDERED.

/s/ Dan Aaron Polster September 13, 2021
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE